

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA
WOODWARD DIVISION**

CONNIE WALDROP and)	
JAMES WALDROP,)	
)	CIVIL ACTION FILE
Plaintiffs,)	
)	NO. <u>CIV-12-532-HE</u>
v.)	
)	
MENTOR WORLDWIDE LLC,)	
ANALYTIC BIOSURGICAL SOLUTIONS,)	
COOPLAST A/S, COOPLAST)	
CORPORATION, and COOPLAST)	
MANUFACTURING, US LLC,)	
)	
Defendants.)	

COMPLAINT

Plaintiffs, by their undersigned counsel, bring this Complaint against Analytical Biosurgical Solutions, Coloplast A/S, Coloplast Corporation, Coloplast Manufacturing U.S., LLC, and Mentor Corporation (collectively referred to herein as "Defendants") related to the design, manufacture, marketing, distribution and sale of Defendants' Aris Transobturator Tape system, (hereinafter "Transvaginal Mesh" or "Aris Transobturator"). This action is for compensatory, equitable, injunctive, and declaratory relief. Plaintiffs make the following allegations based upon their individual personal knowledge as to their own acts, and upon information and belief, as well as upon their attorneys' investigative efforts as to Defendants' actions and misconduct, and allege as follows.

PARTIES AND JURISDICTION

1. Plaintiffs Connie Waldrop and James Waldrop are citizens and residents of the State of Oklahoma.

2. Defendant Mentor Worldwide LLC (“Mentor”) is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 201 Mentor Drive, Santa Barbara, California. Mentor may be served through its registered agent, The Corporation Company, 1833 S Morgan Rd, Oklahoma City, Oklahoma 73128. Mentor was founded in Minneapolis, MN in 1969 and represents that it is a leading supplier of medical products for the global healthcare market. Mentor develops, manufactures and markets innovative, science-based products for the aesthetics, urologic specialties and clinical and consumer healthcare markets around the world. Mentor designed and launched the Aris Transobturator Tape in 2005. Mentor Corporation merged with and into Mentor Worldwide LLC on December 4, 2009. Mentor was acquired by Johnson & Johnson in 2009.

3. Defendant Analytic Biosurgical Solutions (“ABISS”) is a corporation organized and existing under the laws of the Republic of France, maintaining its principal place of business at 14 Rue de la Telematique, St. Etienne, Loire 42000, Republic of France. ABISS’ registered United States Food and Drug Administration (“FDA”) Agent is Elizabeth A. Boots, Coloplast Corporation, 1601 West River Road North, Minneapolis, Minnesota 55411. Ms. Boots is the Vice President of Quality Assurance for Coloplast Corporation.

4. Defendant Coloplast A/S is a corporation organized and existing under the laws of the Kingdom of Denmark maintaining its principal place of business at Holtedam 1, Humlebaek 3050, Kingdom of Denmark, and maintaining its North American principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411. Coloplast A/S does not have an active registration with the Oklahoma Secretary of State, but may be served through its President and CEO, Lars Rasmussen at Holtedam 1, DK-3050, Humlebaek, Denmark. Coloplast A/S moved its North America Headquarters to Minneapolis in June 2006.

5. Defendant Coloplast Corporation (“Coloplast Corp.”) is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411. Coloplast Corp. may be served through its registered agent, National Registered Agents, Inc. of OK, 115 SW 89th St, Oklahoma City, OK 73139. Coloplast Corp. is a wholly owned U.S. sales and marketing subsidiary of Coloplast A/S.

6. Defendant Coloplast Manufacturing US, LLC is a limited liability corporation organized and existing under Delaware law maintaining its principal place of business as 1940 Commerce Drive, North Mankato, MN 56002. Its registered office is 560 Park Street, #6, St. Paul, Minnesota 55103. Coloplast Manufacturing US, LLC, is not currently registered with the Oklahoma Secretary of State. Coloplast Manufacturing US, LLC is a wholly owned subsidiary of Coloplast Corp. Coloplast Corp., Coloplast A/S, and Coloplast Manufacturing US, LLC are collectively referred to herein as “Coloplast.”

7. This is a lawsuit for personal injury damages in excess of \$75,000.00. The parties are citizens of different states. Subject matter jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1332.

8. Defendants are subject to *in personam* jurisdiction in the U.S. District Court for the Western District of Oklahoma because they placed a defective product in the stream of commerce and that product caused personal injuries to Plaintiff Connie Waldrop at her residence in the state of Oklahoma.

FACTUAL BACKGROUND

9. At all relevant times, ABISS was in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, advertising, and delivering, and introducing into interstate commerce, including, *inter alia*, within the United States and,

specifically, within the State of Oklahoma, either directly or indirectly through third parties, subsidiaries or related entities, transvaginal meshes.

10. At all relevant times, Coloplast was in the business of developing, designing, licensing, distributing, selling, marketing, advertising, and delivering, and introducing into interstate commerce including, *inter alia*, within the United States and, specifically, within the State of Oklahoma, either directly or indirectly through third parties, subsidiaries or related entities, transvaginal meshes.

11. At all relevant times, transvaginal meshes were used to treat stress urinary incontinence.

12. Stress urinary incontinence is a type of incontinence caused by leakage of urine during moments of physical stress. It affects 20-40% of all women.

13. Surgical mesh, including transvaginal mesh, is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence. Most transvaginal meshes are comprised of non-absorbable synthetic polypropylene. Upon information and belief, the Aris Transobturator Tape is comprised of a synthetic, petroleum-based mesh.

14. In 1996, the FDA cleared the first mesh product for use in the treatment of stress urinary incontinence (SUI). These products include transvaginal mesh, including the Aris Transobturator Tape, manufactured, marketed, and distributed by Defendants. These products are approved by the FDA under the abbreviated 510k approval process.

15. In May 2005, Mentor announced the U.S. launch of its new Aris(TM) Trans-Obturator Tape. According to Mentor's launch reports, "specifically designed to utilize Mentor's patented Trans-Obturator Technique (T.O.T.(TM)), Aris represents the newest technical achievement and advanced generation of trans-obturator slings for the treatment of stress urinary incontinence in women." "The introduction of Aris furthers Mentor's position as a pioneer of the trans-obturator method for treating stress incontinence in women," commented Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation. "We are committed to driving innovation in the field of women's health to provide better solutions for physicians and the patients they serve." ABISS' FDA registration lists its proprietary device as "Mentor Aris Trans-Obturator Tape and Surgical Kit."

16. On October 12, 2005, ABISS and Mentor entered into a number of agreements pursuant to which ABISS licensed a number of ABISS' products to Mentor which were thereafter marketed by Mentor under its trademarks, including its Aris trademark. On June 2, 2006, Mentor sold its surgical, urological, clinical and consumer healthcare business segments to Coloplast for \$461,145,398, including *inter alia*, Mentor's October 12, 2005, agreements with ABISS and Mentor's Aris trademark.

17. At all times, the product marketed and sold in the United States as "Mentor Aris Trans-Obturator Tape and Surgical Kit" was manufactured by ABISS and, at all times after October 2, 2006, the product "Mentor Aris Trans-Obturator Tape and Surgical Kit" was exclusively marketed and sold in the United States by Coloplast from its principal place of business in Minneapolis, Minnesota.

18. ABISS is registered with the FDA, Registration Number 3004756681, as the manufacturer of "Mentor Aris Trans-Obturator Tape and Surgical Kit" and listed Elizabeth A.

Boots, Coloplast U.S., Vice President, Quality Assurance, as its United States Agent. ABISS is also the assignee of a United States Patent Application for an invention entitled “Implant for the Treatment of Cystocele and Rectocele” “for the treatment of cystocele, rectocele and/or prolapse of the vaginal dome....” United States Patent Application WO/2004/091442 and 2005/0278037 A1.

19. Coloplast’s annual report for 2009-2010 reported that “the majority of our acquired patents and trademarks are associated with the acquisition of Mentor’s urology, business in 2006.” The annual report also said that Mentor signed “a non-competition clause prohibiting Mentor (the seller) from selling urology products for the next seven years....”

20. Coloplast’s website describes its various products, including those for treating (i) “Pelvic Organ Prolapse” and (ii) “Stress Urinary Incontinence”, including “Sling Procedures.” A press release issued by Coloplast described Coloplast’s new corporate headquarters at 1601 West River Road in Minneapolis and stated that “Denmark-based Coloplast... selected north Minneapolis as the new home for its North American headquarters in 2006.” According to the press release the new headquarters “will include one of the company’s three global Innovation Centers.”

21. On July 13, 2011, the FDA issued a new warning regarding serious complications associated with transvaginal mesh, such as the Aris Transobturator Tape manufactured, marketed, and distributed by Defendants. In this warning, the FDA indicated that serious complications associated with the transvaginal mesh were not rare, which was a change from what the FDA reported in October 2008. The FDA had also received increased reports of complications associated with the transvaginal mesh in both pelvic organ prolapse and stress urinary incontinence cases.

22. On August 25, 2011, Public Citizen, a consumer advocacy group, submitted a petition to the FDA seeking to ban the use of transvaginal mesh products in pelvic repair procedures. In its Petition, Public Citizen warned that the transvaginal mesh should be recalled because it offers no significant benefits but exposes patients to serious risks and the potential for permanent life-altering harm. Joining Public Citizen as co-petitioners were Dr. L. Lewis Wall, a professor of obstetrics and gynecology at Washington University in St. Louis, and Dr. Daniel S. Elliott, a urologic surgeon specializing in female urology at the Mayo Clinic in Rochester, Minnesota.

23. On or about June 30, 2006, Plaintiff Connie Waldrop underwent a surgical procedure during which plaintiff's physicians implanted a transvaginal mesh, manufactured, marketed and distributed by Defendants, into Plaintiff. This procedure was done at St. Mary's Regional Medical Center, for treatment of stress urinary incontinence. The transvaginal mesh used in Plaintiff's surgery was Aris Transobturator Tape.

24. The Transvaginal Mesh implanted into Plaintiff on or about June 30, 2006, was designed, manufactured, labeled, tested, advertised, marketed, distributed, and sold by Defendants in Oklahoma to be used by surgeons to treat pelvic organ prolapse and stress urinary incontinence and was represented by Defendants to be an appropriate and suitable product for such purpose.

25. Subsequent to the implant of her transvaginal mesh device, Plaintiff presented to her physician with complaints of pain and irritation in the area of her original implant. Plaintiff was subsequently found to have complications which are directly attributable to the Aris Transobturator Tape.

26. As a direct and proximate result of Defendants' conduct and omissions, Plaintiff has suffered, and continues to suffer, multiple, severe and painful personal injuries, including, but not limited to, dyspareunia (painful sexual intercourse), continued incontinence, erosion of the mesh implant, swelling, pelvic pain, groin pain, and an impairment of the relationship between husband and wife. Plaintiff underwent a revision procedure on May 23, 2010, at St. Mary's Regional Medical Center to extract fibers of the eroded mesh.

27. As a direct and proximate result of Defendants' conduct and omissions, Plaintiffs have also incurred substantial medical, healthcare, incidental and related expenses and will continue to incur such expenses in the future.

CLAIMS FOR RELIEF

COUNT I
NEGLIGENCE

28. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

29. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertising, supplying, promoting, packaging, sale, and distribution of transvaginal mesh, including the duty to assure that the Aris Transobturator Tape would not cause users to suffer unreasonable, dangerous side effects.

30. Defendants failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promoting, advertising, packaging, sale, testing, quality assurance, quality control, and distribution of Aris Transobturator Tape because Defendants knew or had reason to know that using transvaginal mesh, including, but not limited to, Aris Transobturator Tape, created a high risk of unreasonable and dangerous side effects, including, but not limited to, severe erosion of the vaginal wall and other tissues, infection, the loss of the

ability to perform sexually, death and other severe personal injuries, which are permanent and lasting in nature, including, but not limited to, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, a future of high-risk pregnancies, and any and all further medical complications, such as Plaintiff's need for life-long medical treatment and care, and fear of developing further adverse health consequences.

31. Defendants manufactured, produced, promoted, formulated, created, developed, designed, sold, and distributed transvaginal mesh, including but not limited to Aris Transobturator Tape, without thoroughly and adequately testing them;

a. Defendants manufactured, produced, promoted, advertised, formulated, created, developed, designed, and distributed its transvaginal meshes, including but not limited to Aris Transobturator Tape, while concealing and suppressing test results;

b. Defendants did not conduct sufficient studies and tests to determine whether its transvaginal meshes were safe for their intended use, because Defendants knew, or should have known, that its transvaginal meshes were unsafe and unfit for use by reason of the dangers to their users;

c. Defendants failed to warn Plaintiff, her physicians and her other healthcare providers, the medical and healthcare community, or the public as soon as Defendants knew, or should have known, that the dangers of the use of transvaginal mesh, including, but not limited to, the Aris Transobturator Tape, were much higher than the risk of adverse effects from other, safer alternative treatments for stress urinary incontinence;

d. Defendants concealed, suppressed, failed to warn about and failed to follow up on, the adverse results of clinical testing which determined that transvaginal meshes had a high risk of serious and dangerous adverse health effects and consequences;

e. Defendants failed to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with and, more particularly, use transvaginal meshes, including, but not limited to, Aris Transobturator Tape;

f. Defendants advertised and recommended the use of transvaginal meshes, including, but not limited to, Aris Transobturator Tape, while suppressing and concealing dangers they knew to be inherent in the use of transvaginal meshes;

g. Defendants represented that their transvaginal meshes were safe for their intended use when Defendants knew, or should have known, that their transvaginal meshes were unsafe for their intended use. Defendants represented that transvaginal mesh, including, but not limited to, Aris Transobturator Tape, were just as safe as other treatments for stress urinary incontinence when Defendants knew, or should have known, that transvaginal meshes, including, but not limited to, Aris Transobturator Tape, had a high risk of serious and dangerous adverse health effects and consequences as a result of which Defendants' transvaginal meshes were not as safe as other treatments for stress urinary incontinence;

h. Defendants suppressed, concealed, and omitted information concerning warnings, recommendations, and observations about transvaginal meshes from Plaintiff, her physicians, and her other healthcare providers and from the public, while knowing

that transvaginal meshes, including, but not limited to, the Aris Transobturator Tape, were unsafe and dangerous; and

i. Defendants suppressed, concealed, omitted, and misrepresented to Plaintiff, her physicians and her other healthcare providers, the medical community, the public, the severity of the risks and the dangers inherent in the intended use of transvaginal meshes, including, but not limited to, Aris Transobturator Tape, as compared to other treatments for stress urinary incontinence.

32. Defendants were negligent in the design, research, development, manufacture, promotion, packaging, advertising, distribution, testing, marketing, and sale of transvaginal meshes, including but not limited to Aris Transobturator Tape, because:

a. Defendants failed to use due care in the design, research, manufacture, and development of its transvaginal meshes so as to avoid risks to patients of serious and dangerous adverse health effects and consequences when its transvaginal meshes were used for the treatment of stress urinary incontinence;

b. Defendants failed to design and manufacture its transvaginal meshes so as to minimize the risk of serious side effects, including, but not limited to, the erosion of the vaginal wall and infections; and

c. Defendants failed to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance, to determine the safety of transvaginal meshes.

33. While Defendants knew, or should have known, that transvaginal meshes caused unreasonably dangerous side effects, Defendants nonetheless continued and still continue to

market, manufacture, distribute, advertise, promote, and sell transvaginal meshes, including, but not limited to, Aris Transobturator Tape, to consumers.

34. Defendants knew, or should have known, that consumers such as Plaintiff, into whom transvaginal meshes were implanted, would foreseeably suffer severe injuries as a result of Defendants' failure to exercise ordinary care, as set forth above.

35. Defendants' negligence was the proximate cause of the injuries, harm, and economic loss that Plaintiff has suffered and will continue to suffer in the future.

36. As a direct, foreseeable and proximate result of Defendants' aforesaid acts and omissions, and as the direct, foreseeable and proximate result of the implantation of Defendants' transvaginal mesh into Plaintiff, Plaintiff was caused to suffer, did suffer and will continue to suffer from physical, emotional, economic and other injury.

COUNT II
STRICT LIABILITY: DEFECTIVE DESIGN

37. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

38. At all relevant times, Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold and distributed, transvaginal mesh, including, but not limited to, Aris Transobturator Tape, which was implanted into Plaintiff.

39. Defendants' transvaginal mesh was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with Defendants' transvaginal meshes without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

40. At all relevant times, Defendants' transvaginal mesh was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Plaintiff.

41. Defendants' transvaginal mesh, including, but not limited to, Aris Transobturator Tape, was defective in design and formulation in that, when it left Defendants' hands, the foreseeable risks exceeded the benefits allegedly associated with the design of the transvaginal mesh.

42. Defendants' transvaginal mesh was defective in design because, when it left the Defendants' hands, it was unreasonably dangerous and also was more dangerous than the ordinary consumer would expect.

43. At all relevant times, Defendants' transvaginal meshes were in a defective condition and were unsafe, and Defendants knew, or should have known, that their transvaginal meshes were defective and unsafe, especially when used in the manner instructed and provided by Defendants.

44. Defendants knew, or should have known, at all relevant times, that the transvaginal mesh, including, but not limited to, the Aris Transobturator Tape, was in a defective condition, and was and is inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

45. At the time that the Aris Transobturator Tape was implanted into Plaintiff, it was being used for its intended use in a manner normally intended, namely to treat stress urinary incontinence

46. Defendants had a duty to create a product, to wit, its transvaginal mesh, including but not limited to the Aris Transobturator Tape, that was not unreasonably dangerous for its normal, common, intended use.

47. Defendants' transvaginal mesh, including, but not limited to, the Aris Transobturator Tape, was manufactured defectively because it left the hands of Defendants in a defective condition and was unreasonably dangerous for the intended use for which it was designed, manufactured and sold.

48. Defendants designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product, to wit, transvaginal mesh, including, but not limited to, Aris Transobturator Tape, that created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are, therefore, strictly liable for the injuries and damages sustained by Plaintiff.

49. Plaintiff, her physicians and her other healthcare providers could not, by the reasonable exercise of care, have discovered the defects in this product or perceived their danger.

50. Defendants' transvaginal mesh, including, but not limited to, the Aris Transobturator Tape, was defective due to inadequate warnings and instructions, because Defendants knew or should have known that the transvaginal mesh created a risk of serious and dangerous side effects, including, but not limited to, erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, loss of the ability to perform sexually, and other serious and severe personal injuries which are permanent and lasting in nature; and Defendants failed to test adequately for or to warn of these risks.

51. Defendants' transvaginal mesh was defective due to inadequate post-marketing surveillance and warnings because Defendants knew, or should have known, the risks of serious

side effects, including, but not limited to, erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and the loss of the ability to perform sexually.

52. Defendants also failed to provide adequate warning for use to consumers of the transvaginal meshes, and Defendants continue improperly to advertise, to market, to label, and to promote transvaginal mesh to the public and to the medical community.

53. By reason of the foregoing, Defendants are strictly liable in tort to Plaintiff.

54. The defective design of Defendants' transvaginal mesh and Defendants' over-marketing through advertisements, together with their failure to provide adequate warnings accompanying the transvaginal mesh were willful, wanton, and reckless.

55. The defects in Defendants' transvaginal meshes were substantial and contributing factors in causing Plaintiff's injuries.

56. As a direct, foreseeable and proximate result of Defendants' aforesaid acts and omissions, and as the direct, foreseeable and proximate result of the implantation of Defendants' transvaginal mesh into Plaintiff, Plaintiff was caused to suffer, did suffer and will continue to suffer from physical, emotional, economic and other injury.

COUNT III
STRICT LIABILITY: FAILURE TO WARN

57. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

58. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released Transvaginal Mesh into the stream of commerce within the State of Oklahoma and elsewhere, and directly advertised and marketed within the State of Oklahoma and elsewhere, Transvaginal Mesh to consumers or

persons responsible for consumers, and, therefore, had a duty to warn of the risks associated with the use of Transvaginal Mesh.

59. Defendants' Transvaginal Mesh, including, but not limited to, the Aris Transobturator Tape, was under the exclusive control of Defendants and was not accompanied by adequate warnings regarding adverse side effects and complications associated with the use of Transvaginal Mesh, or by adequate warnings regarding the comparative severity, duration and extent of the risk of injuries associated with use of Transvaginal Mesh.

60. Defendants failed to timely and reasonably to warn of material facts regarding the safety and efficacy of Transvaginal Mesh; no healthcare provider would have prescribed — and no consumer would have used —Transvaginal Mesh had the facts concerning the safety and efficacy of Transvaginal Mesh been made known to such healthcare providers and consumers.

61. Defendants' advertising campaign for Transvaginal Mesh did *not* advise either consumers or healthcare providers that Transvaginal Mesh presented multiple and dangerous medical risks, including erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and the loss of the ability to perform sexually.

62. Defendants failed to perform or otherwise facilitate adequate testing; such testing which would have demonstrated that Transvaginal Mesh posed serious and potential life threatening side effects and complications with respect to which full and proper warning accurately and fully reflecting the symptoms, scope and severity should have been made to healthcare providers, to the FDA, and to consumers, including Plaintiff.

63. Transvaginal Mesh was defective due to inadequate post-marketing warnings and instructions because, after Defendants knew, or should have known, of the risk of serious and potentially life threatening side effects and complications from the use of Transvaginal Mesh,

Defendants failed to provide adequate warnings to healthcare providers or to the consuming public, including Plaintiff, and instead continued to advertise and market Transvaginal Mesh aggressively.

64. As a direct, foreseeable and proximate result of Defendants' foregoing conduct, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT IV
BREACH OF EXPRESS WARRANTIES

65. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

66. Defendants expressly warranted that their Transvaginal Mesh, including, but not limited to, the Aris Transobturator Tape, was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

67. At the time of Defendants' aforesaid express warranties, Defendants knew or should have known, that their transvaginal mesh did not conform to these express warranties because their transvaginal mesh were not safe and had numerous serious side effects, about which Defendants did not adequately warn.

68. As a direct, foreseeable, and proximate result of Defendants' breach of their express warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm and economic loss.

69. Plaintiff relied on Defendants' express warranties with respect to their transvaginal meshes.

70. Members of the medical community, including Plaintiff's physicians and other healthcare providers, relied upon Defendants' representations and warranties in connection with the use, recommendation, description, and implantation of Transvaginal Mesh.

71. Defendants breached the express warranties because their Transvaginal Mesh was, and is, defective and unreasonably unsafe for its intended use.

72. Defendant expressly represented to Plaintiff, her physicians and her other healthcare providers that its transvaginal meshes (i) were safe and fit for the purposes intended, (ii) were of merchantable quality, (iii) did not produce any dangerous side effects in excess of those risks associated with other treatments for pelvic organ prolapse and stress urinary incontinence, (iv) the side effects they produced were accurately reflected in ABISS' warnings, and (v) they were adequately tested and fit for their intended use.

73. Defendants knew, or should have known, that their aforesaid representations and warranties were false, misleading, and untrue because its transvaginal meshes were not safe and fit for their intended use, and caused their users serious injuries of which Defendants did not adequately warn.

74. As a direct, foreseeable and proximate result of Defendants' foregoing acts and omissions, Plaintiff was caused to suffer and did suffer serious and grievous personal injuries, including erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and the loss of the ability to perform sexually, as well as other grievous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff's need for life-long medical treatment and medical monitoring, and perpetual fear of developing additional adverse health consequences.

75. As a direct, foreseeable and proximate result of Defendants' foregoing conduct, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT V
BREACH OF IMPLIED WARRANTIES

76. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

77. At all relevant times, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and sold Transvaginal Mesh to treat stress urinary incontinence.

78. At the time Defendants marketed, sold, and distributed Transvaginal Mesh for implantation into Plaintiff, Defendants knew of the intended use of the Transvaginal Mesh, and impliedly warranted the Transvaginal Mesh to be of merchantable quality and safe and fit for such intended use.

79. Defendants impliedly represented and warranted to Plaintiff, her physicians and other healthcare providers, to the general public, that Transvaginal Mesh was safe and of merchantable quality and fit for the ordinary purpose for which Transvaginal Mesh was to be used.

80. Defendants' representations and warranties were false, misleading, and inaccurate because Transvaginal Meshes were unsafe, unreasonably dangerous, improper, not of merchantable quality and otherwise defective.

81. Plaintiff, her physicians and her other healthcare providers relied on Defendants' superior skill and judgment, as to whether Transvaginal Meshes were of merchantable quality

and safe and fit for their intended use, and as to whether Transvaginal Meshes were fit for this particular use.

82. Defendants put Transvaginal Meshes into the stream of commerce within the State of Minnesota and elsewhere, in a defective, unsafe, and inherently dangerous condition, and Transvaginal Meshes were expected by Defendants to and did reach Plaintiff without substantial change in the condition in which Transvaginal Meshes were sold.

83. Defendants breached their implied warranty because Transvaginal Meshes were not fit for their intended use and purpose.

84. As a direct, foreseeable and proximate result of Defendants' aforesaid acts and omissions within the State of Oklahoma, Plaintiff was caused to suffer, and did suffer, serious and dangerous side effects of erosion of the vaginal wall and other tissues, permanent and substantial physical deformity, and the loss of the ability to perform sexually and has undergone corrective surgeries and may need further corrective surgery. Plaintiff has suffered other grievous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff's need for life-long medical treatment and care, medical monitoring, and perpetual fear of developing additional adverse health consequences.

85. As a direct, foreseeable and proximate result of Defendants' foregoing conduct, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT VI
UNJUST ENRICHMENT

86. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

87. Defendants are, and at all times were, the manufacturer, seller, and/or supplier of Transvaginal Mesh.

88. Plaintiff paid for Transvaginal Mesh for the purpose of treating stress urinary incontinence.

89. Defendants accepted payment from Plaintiff for the purchase of Transvaginal Mesh.

90. Plaintiff has not received the safe and effective Transvaginal Mesh for which she paid. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff was not receiving a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiff, as a reasonable consumer, expected.

91. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled to in equity, and hereby seeks, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

COUNT VII
COMMON LAW FRAUD

92. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

93. Defendants falsely and fraudulently represented to Plaintiff, her physicians and her other healthcare providers, to the medical and healthcare communities, and to the public that Transvaginal Mesh had been tested and had been determined to be safe and effective to treat stress urinary incontinence.

94. When Defendants made their aforesaid representations Defendants knew, or should have known, that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the falsity of their representations as well as the dangers and health risks to users of Transvaginal Meshes, including Plaintiff.

95. Defendants made the aforesaid representations with the intent of defrauding and deceiving Plaintiff, her physicians and her other healthcare providers, the medical and healthcare communities, and the public, and to induce Plaintiff, her physicians and her other healthcare providers, the medical and healthcare communities and the public, to recommend, purchase and implant Transvaginal Mesh to treat stress urinary incontinence, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of plaintiff and other consumers.

96. In representations to Plaintiff, her physicians and her other healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

- a. Transvaginal Meshes are not as safe as other forms of treatment for stress urinary incontinence;
- b. The risk of adverse events with Transvaginal Meshes was not adequately tested and was known by Defendants;
- c. Defendants deliberately failed to follow up on the adverse results from clinical studies and buried and misrepresented those results;

d. Defendants were aware at all times of the dangers in Transvaginal Meshes, in addition to, and above and beyond the risks normally associated with treating stress urinary incontinence;

e. Transvaginal Meshes were defective, and caused dangerous and adverse side effects, including, but not limited to, erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and loss of the ability to perform sexually, at a much more significant rate than other treatments for stress urinary incontinence;

f. Patients with Transvaginal Meshes implanted need to be monitored more regularly than patients treated with other treatments for stress urinary incontinence;

g. Transvaginal Meshes were manufactured negligently;

h. Transvaginal Meshes were manufactured defectively; and

i. Transvaginal Meshes were designed negligently and defectively.

97. Defendants had a duty to disclose to Plaintiff, her physicians and her other healthcare providers, the defective nature of Transvaginal Meshes, including, but not limited to, the fact that Transvaginal Meshes had heightened risks of dangerous side effects.

98. Defendants had sole access to the facts concerning the defective nature of Transvaginal Meshes and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons into whom Transvaginal Meshes were implanted, including Plaintiff.

99. Defendants' aforesaid concealment and omissions of material fact concerning the safety of Transvaginal Meshes were made intentionally, willfully, wantonly, and recklessly to mislead, to cause Plaintiff's physicians and her other healthcare providers to purchase and to

implant Transvaginal Meshes, and to mislead Plaintiff into reliance and to cause Plaintiff to permit Transvaginal Meshes to be implanted into her.

100. At the time that Defendants made these representations, and at the time Transvaginal Meshes were implanted into Plaintiff, Plaintiff was unaware of the falsehood of Defendants' aforesaid representations, reasonably believed them to be true, and relied upon them.

101. Defendants knew, or should have known that Transvaginal Meshes could and would cause severe and grievous personal injury to women into whom they were implanted and that Transvaginal Meshes were inherently dangerous in a manner that exceeded any purported benefit from the use of Transvaginal Meshes and any warnings gave concerning Transvaginal Meshes.

102. In reliance upon Defendants' false representations, Plaintiff was induced to, and did permit Transvaginal Meshes to be implanted into her, thereby sustaining severe and permanent personal injuries and damages. Defendants knew, or should have known, that Plaintiff, her physicians and her other healthcare providers had no way to determine that Defendants concealed and omitted facts necessary to make the statements Defendants made about Transvaginal Meshes true.

103. Plaintiff, her physicians and her other healthcare providers reasonably relied on Defendants' statements and representations which suppressed and concealed facts that were critical to understanding the dangers inherent in the use of Transvaginal Meshes.

104. As a result of Defendants' research, clinical trials, testing or lack thereof, Defendants intentionally distributed false information and made false statements and representations, including, but not limited to, assuring Plaintiff, her physicians, and her other

healthcare providers and the public that Transvaginal Meshes were safe to treat stress urinary incontinence. Defendants intentionally omitted, concealed and suppressed the results of their research, clinical trials and testing from Plaintiff, her physicians and her other healthcare providers and the public.

105. Defendants had a duty when disseminating information to the public, including Plaintiff, to disseminate truthful information; and defendants had a parallel duty not to deceive the public, Plaintiff, Plaintiff's physicians and plaintiff's other healthcare providers.

106. The information Defendants distributed to Plaintiff, her physicians, and her other healthcare providers, to the public, and to the medical community, included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing representations, which were materially false and misleading, and which contained material omissions of the truth about the dangers of the use of Transvaginal Meshes.

107. Defendants misrepresented to Plaintiff, her physicians and her other healthcare providers, to the healthcare and medical communities, and to the public, the material facts that Transvaginal Meshes did not have dangerous or serious adverse health safety concerns, and that Transvaginal Meshes were as safe as other means of the treatment of stress urinary incontinence.

108. Defendants' intent in making these misrepresentations was to deceive and defraud and to gain the confidence of Plaintiff, her physicians and her other healthcare providers, the medical community, and the public and to induce Plaintiff, her physicians and her other healthcare providers, the healthcare and medical communities, and the public to request, recommend, and implant Transvaginal Meshes into patients, including Plaintiff.

109. Defendants made claims and representations in reports to the public and to healthcare professionals and in advertisements that Transvaginal Meshes did not present serious health risks.

110. Defendants' aforesaid representations were knowingly false when made or were made recklessly and without regard to the true facts.

111. Defendants' aforesaid representations were made with the intention of deceiving and defrauding Plaintiff, her physicians and her other healthcare providers and other members of the healthcare and medical communities, were made in order to induce Plaintiff, her physicians and her other healthcare providers to dispense, recommend, and implant Transvaginal Meshes into Plaintiff.

112. Defendants intentionally concealed, omitted and misrepresented the dangerous and serious health and safety concerns inherent in the use of the Transvaginal Meshes for the purpose of influencing the sales of a product known to Defendants to be dangerous and defective, and certainly not as safe as other alternatives for treating stress urinary incontinence.

113. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving Plaintiff, her physicians and her other healthcare providers, into a false sense of security, to induce Plaintiff's physicians and other healthcare providers to recommend, dispense, and implant Transvaginal Meshes into Plaintiff, and to induce Plaintiff to permit Transvaginal Meshes to be implanted into plaintiff.

114. Plaintiff and her healthcare providers relied to their detriment on Defendants' misrepresentations and omissions. Had Plaintiff known the truth about the dangers and serious

health and safety risks of Transvaginal Meshes, Plaintiff would not have permitted Transvaginal Meshes to be implanted into her.

115. Defendants' fraud and deceit was perpetrated willfully, wantonly, and purposefully on Plaintiff.

116. As a direct, foreseeable and proximate result of Defendants' aforesaid acts and omissions Plaintiff was caused to suffer, and did suffer, the serious and dangerous side effects of erosion of the vaginal wall and other tissues, permanent and substantial physical deformity and loss of the ability to perform sexually, has undergone corrective surgeries and will likely require further corrective surgery, and suffered further grievous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff's need for life-long medical treatment and care, medical monitoring and perpetual fear of developing additional adverse health consequences.

117. As a direct, foreseeable and proximate result of Defendants' foregoing conduct, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT VIII
NEGLIGENT MISREPRESENTATION

118. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

119. Defendants had the duty to accurately and truthfully represent to the medical and healthcare communities, to Plaintiff, her physicians and her other healthcare providers, and to the public, that Transvaginal Meshes had been tested and had been determined to be safe and

effective for treating stress urinary incontinence. Defendants' representations of safety and effectiveness of Transvaginal Meshes were false.

120. Defendants failed to exercise ordinary care in their representations concerning Transvaginal Meshes because Defendants negligently concealed, omitted and misrepresented Transvaginal Meshes' high risk of unreasonable, dangerous, adverse side effects.

121. Defendants knew, or should have known, that Transvaginal Meshes had been insufficiently tested, or had not been tested at all, lacked adequate and accurate warnings, and created a high risk, or higher than acceptable risk, or higher than reported and represented risk, of adverse side effects, including, but not limited to, erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and loss of the ability to perform sexually.

122. As a direct, foreseeable and proximate result of defendants' wrongful acts and omissions, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT IX
LOSS OF CONSORTIUM

123. Plaintiffs incorporate all of the allegations contained in the foregoing paragraphs of this Complaint in their entirety as if fully rewritten herein.

124. Plaintiff James Waldrop is the spouse of Plaintiff Connie Waldrop, and as a direct and proximate result of Defendant's conduct as described in this Complaint, Plaintiff James Waldrop has necessarily paid and has become liable to pay for medical aid, treatment, attendance and medications, and will necessarily incur further expenses of a similar nature in the future.

125. As a direct and proximate result of Defendant's conduct as described in this Complaint, Plaintiff James Waldrop suffered and in the future will suffer the loss of his wife's affection, companionship, services, society and other damages.

126. As a direct and proximate result of Defendant's conduct as described in this Complaint, Plaintiff James Waldrop is entitled to and hereby seeks all such compensatory damages, punitive damages, attorney fees, reimbursement for all past, present and future health and medical care costs related to the Products, and any and all other damages allowed by law, in an amount to be determined at trial.

PUNITIVE DAMAGES

127. At the time Defendants designed, manufactured, marketed, labeled, packaged, and sold the dangerous and defective Product and failed to adequately warn Plaintiff of the dangerous and defective nature of the Product and thereby caused Plaintiff's injuries, Defendants knew, or in the exercise of the appropriate degree of care should have known, that its conduct created a high degree of probability of injury to others and thereby showed complete and reckless indifference to, and conscious disregard for the safety of others, including Plaintiff, and such conduct warrants the imposition of punitive damages under all applicable legal standards.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages according to proof and in an amount to fully compensate Plaintiffs for all of their injuries and damages, both past and present;
2. Special damages according to proof and in an amount to fully compensate Plaintiffs for all of their injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health

care, lost income, permanent disability, including, permanent instability and loss of balance, and pain and suffering;

3. All other damages as allowed by law;
4. Disgorgement of profits; and
5. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiffs hereby demand a jury trial on all claims so triable in this action.

Dated: May 10, 2012

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